



PATENT #141
Docket No. 377882001420
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Rhea Amid
Rhea Amid

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of:

Gary VAN NEST, Stephen TUCK,
Karen L. FEARON and Dino DINA

Serial No.: 09/927,422

Filing Date: August 10, 2001

For: BIODEGRADABLE
IMMUNOMODULATORY
FORMULATIONS AND METHODS
FOR USE THEREOF

Examiner: T. Gibbs

Group Art Unit: 1635

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RESPONSE TO RESTRICTION REQUIREMENT

Mail Stop Non-Fee Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This is in response to the Office Action dated May 1, 2003 (Paper No. 13) which sets forth a restriction requirement for pending claims 1-84 in the above-identified application. A response to this action is due June 1, 2003. Accordingly, this response is timely filed.



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ELECTION OF INVENTION

Claims 1-84 are pending in this application. Restriction has been required as between the following allegedly distinct groups of inventions:

Group I (claims 1-19, 22-23, 48-65, 68-76, and 79-82): drawn to an immunomodulatory polynucleotide/microcarrier (IMP/MC) complex and a kit comprising said immunomodulatory polynucleotide/microcarrier (IMP/MC) complex, classifiable in class 536, subclass 24.3;

Group II (claims 1, 11-14, 18, 20-21, 66-67, 77-78, 81, and 83-84): drawn to an immunomodulatory polynucleotide/microcarrier (IMP/MC) complex and a kit comprising said immunomodulatory polynucleotide/microcarrier (IMP/MC) complex wherein said complex further comprises an antigen, classifiable in class 536, subclass 24.1;

Group III (claims 24-43 and 46-47): drawn to a method of modulating an immune response in an individual comprising administering to an individual a composition comprising an immunomodulatory polynucleotide/microcarrier (IMP/MC) complex, classifiable in class 435, subclass 4; and

Group IV (claims 24, 35-38, 42 and 44-45): drawn to a method of modulating an immune response in an individual comprising administering to an individual a composition comprising an immunomodulatory polynucleotide/microcarrier (IMP/MC) complex, wherein said composition further comprises an antigen, classifiable in class 435, subclass 7.22.

Applicants hereby elect Group I (claims 1-19, 22-23, 48-65, 68-76, and 80-82), with traverse. Applicants expressly reserve their right under 35 U.S.C. § 121 to file a divisional application directed to the nonelected subject matter during the pendency of this application, or an application claiming priority from this application.

As an initial matter, Applicants respectfully point out that the claims separated into the Groups II and IV do not conform with the description given for each group. In Group II, claims 1, 11-14, 18 and 81 do not recite that the complex further comprises an antigen. In Group IV, claims 24, 35-38 and 42 do not recite that the composition further comprises an antigen. Applicants respectfully request that the Examiner correct the listing of claims in these groups should the restriction requirement be upheld with respect to any of the groups.

In support of the restriction between Groups I and II, the Examiner states that the groups are unrelated because they employ different molecules so that independent searches of the prior art would be required.

Applicants respectfully disagree. The claims of the two groups are related by a genus-species relationship and a search of the genus (Group I) would encompass the search of the species (Group II).

Further, Applicants respectfully traverse the classification differences of Groups I and II. The classification definitions of the Office list Group I (class 536, subclass 24.3) as involving probes for detection of specific nucleotide sequences or primers for synthesis of DNA or RNA and Group II (class 536, subclass 24.1) as involving noncoding sequences which control transcription or translation processes. Applicants submit that the claims are directed to immunomodulatory polynucleotide/microcarrier complexes and do not appear to fall under these classifications. Applicants respectfully submit that the Examiner has not provided adequate explanation for distinguishing the classification of these two groups.

In support of the restriction between Groups III and IV, the Examiner also states that the groups are unrelated because they employ different molecules so that independent searches of the prior art would be required. Again, Applicants respectfully disagree. The claims of the two groups are related by a genus-species relationship and a search of the genus (Group III) would encompass the search of the species (Group IV).

Further, Applicants respectfully traverse the classification differences of Groups III and IV. The classification definitions of the Office list Group III (class 435, subclass 4) as involving processes in which there is a measurement or test of a material which contains an enzyme or microorganism or processes in which a material containing an enzyme or microorganism is used to perform a measurement or test, and Group IV (class 435, subclass 7.22 indented under subclass 4) as involving a measurement or test involving antigen-antibody binding, specific binding protein assay or specific ligand-receptor binding assay. Applicants submit that the claims are directed to methods of modulating an immune response comprising administering an immunomodulatory polynucleotide/microcarrier complex and do not appear to fall under these classifications. Applicants respectfully submit that the Examiner has not provided adequate explanation for distinguishing the classification of these two groups.

Applicants also traverse the separation of the claims of Groups I/II and III/IV as allegedly separate invention. The product of the Group I/II claims is an immunomodulatory polynucleotide/microcarrier (IMP/MC) complex and the Group III/IV claims are drawn to a method of modulating an immune response comprising administering an IMP/MC complex. The Examiner states that "the immunomodulatory polynucleotide/microcarrier (IMP/MC) complex of Groups I and II can be used as a hybridization probe, which is a materially different process than a method of modulating an immune response in an individual comprising administering to an individual a composition comprising an immunomodulatory polynucleotide as in Groups III and IV." Office Action, page 5. Applicants respectfully point out that the claims of Groups III and IV recite administration of the IMP/MC complex, not simply an immunomodulatory polynucleotide. Applicants also note that the Examiner has provided no support for the assertion that the IMP/MC complex can be used as a hybridization probe. Applicants request that the Examiner support the assertion that the product (Group I/II) and the method of using the product (Group III/IV) are distinct inventions or withdraw the requirement to separate groups (M.P.E.P. §806.05(h)).

Should the Examiner uphold the restriction requirement with respect to Groups I/II and III/IV and the product claim is subsequently found allowable, Applicants reserve the right to request rejoinder of withdrawn process claims which include all the limitations of the allowable product claim for examination (M.P.E.P. §821.04).

CONCLUSION

Applicants request reconsideration of the restriction requirement and examination of the elected subject matter on the merits.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicants petition for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. 3777882001420. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

Dated: May 30, 2003

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<h1 style="margin: 0;">TRANSMITTAL FORM</h1> <p style="margin: 5px 0;">(to be used for all correspondence after initial filing)</p>	Application Number	09/927,422	
	Filing Date	August 10, 2001	
	First Named Inventor	Gary VAN NEST	
	Group Art Unit	1635	
	Examiner Name	T. Gibbs	
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<div style="border: 1px solid black; width: 100px; height: 20px; float: left; margin-right: 10px;">Remarks</div>		<p style="font-size: 1.5em; font-weight: bold;">25225</p> <p style="font-size: 0.8em;">PATENT TRADEMARK OFFICE</p>

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT	
Firm or Individual Name	MORRISON & FOERSTER LLP Karen Zachow - 46,332
Signature	<i>Karen R Zachow</i>
Date	May 30, 2003

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Dated: 5-30-03 Signature: *Rhea Amid* (Rhea Amid)